

# **Texas Vaccines for Children Provider Compliance Policy**

## **POLICY:**

As the cost of childhood vaccines increases and the complexity of immunization programs grow, the federal and state Vaccines for Children (VFC) programs become more vulnerable to fraud and abuse. The information within this policy will guide Health Service Regions, Local Health Departments and Austin Office staff to: (1) identify high risk non-compliance issues, (2) prevent re-occurrence through education and training, and determine when referral to Texas State Office of Inspector General (OIG) is appropriate.

## **DEFINITIONS:**

Primary Education – Occurs during the initial VFC enrollment or new staff training. This education includes orientation/updates to the VFC Operations.

Secondary Education – Occurs when addressing moderate compliance issues. Moderate could include initial serious non-compliance activities, or repeat minor non-compliance. Secondary education is performed when a “No” is recorded on a QA On-Site Evaluation Report. Education is done on site at the time of the visit and follow-up occurs at five or 10 days, and at six months depending on the question. Follow-up can be performed by site visit, phone call, or letter. Secondary education may also include routine individual training, and TVFC provider educational meetings.

Formal Intervention Education – Targets education or training on how to correct the situation in areas of identified need.

Tertiary Education – Occurs when serious compliance issues, immediate and significant actions must occur to correct situation. 1) Is the non-compliant behavior causing or has it caused loss of TVFC vaccine? 2) Is the behavior placing the TVFC Program in *danger* if the behavior is not stopped immediately? 3) Has the provider received unintentional financial gain because of the behavior?

Danger – An action that places the program at risk for unintentional fraud or abuse; or provider actions placing TVFC children at risk.

Referral to External Agency – Provider actions that represent intentional fraud and/or abuse of the TVFC Program.

Primary Contacts – All cases of suspected fraud or abuse should be reported to the following individuals in the Austin Office (AO), who will; 1) confer with HSR managers regarding if and where identified potential fraud/abuse situations are to be referred; 2) identify the appropriate source to make the referral; and 3) notify appropriate governmental agencies (CDC, state Medicaid and others as appropriate).

Vaccine Services Group (VSG) Manager, Primary  
VSG Operations Coordinator, back-up  
VSG Projects Coordinator, back-up

Enforcement Agencies – The Texas State Office of Inspector General (OIG) receives reports of suspected fraud and abuse as directed by OIG procedures. Reporting may come from the Immunization Branch, any other private or public entity, or individual. After receiving a report, OIG will:

- Conduct a preliminary screening to determine if the report warrants a full scale investigation;
- Perform a field investigation; and if necessary;
- Conduct a full scale investigation;
- Develop a final report, and if necessary;
- Submit findings to Office of Attorney General (OAG) for further action.

The OIG and OAG have an Interagency Contract to define the duties and obligations of each agency.

**Note:** Once a case is referred to the OIG, the OIG office will only confirm a case is pending. It will not be possible to get details of the case until the investigation is complete and the final report is drafted. OIG is working with the Texas Immunization Branch to develop a system to forward those reports once finalized. The investigation process varies in time with the complexity of cases, and some cases can take years to complete.

## **PROCEDURES:**

### **I. Non-Compliance Identified During On-Site Visit**

#### **Secondary Education**

Secondary Education is performed any time a provider site receives a “NO” response on the On-Site Evaluation Report. The prescribed timeframe for this follow-up is identified in the *TVFC Operations Manual (Section Three: Program Evaluation, I. TVFC Visits, A. Site Monitoring Activities)*. Secondary education includes contacting the provider and addressing each problem with the appropriate education and resources identified in the TVFC Quality Assurance Tool Resource Manual (by question). Secondary Education may be preformed via phone call, letter, or site visit, whichever method is deemed appropriate by the overseeing agency.

#### **A. High-risk questions that require Formal Intervention, Tertiary education, and follow-up.**

- 12. Vaccines provided regardless of inability to pay.**
- 14. Administration fee is less than or equal to the maximum fee.**
- 48a. Appropriate refrigerators/freezers are used to store vaccine.**
- 50a. Refrigerator/freezer temperature log is available for the last three months.**
- 50d. From the logs provided, all recorded refrigerator temperatures are within the recommended range.**
- 51c. From the logs provided, all recorded freezer temperatures are within the recommended range.**
- 55. A physical inventory of vaccine is done monthly.**
- 57. The loss/gain is less than 5%.**
- 59. TVFC vaccines can be distinguished from private stock.**
- 61a. All clients are screened for eligibility.**

## **B. Correction process**

### **1. Previous Compliance Issues**

If staff identifies a provider for which secondary education has proven unsuccessful, they should begin the next phase of Formal Intervention.

### **Formal Intervention Education**

**12. Vaccines provided regardless of inability to pay.**

**14. Administration fee is less than or equal to the maximum fee.**

**50a. Refrigerator/freezer temperature log is available for the last three months.**

**55. A physical inventory of vaccine is done monthly.**

**57. The loss/gain is less than 5% (Accounting Column).**

**59. TVFC vaccines can be distinguished from private stock (no private vaccine, but profile indicates insured children in practice).**

**61a. All clients are screened for eligibility.**

#### **Education for these questions (12, 14, 50a, 55, 57, 59, 61a):**

- Provide appropriate education associated with high-risk non-compliance issue using memos, TVFC guidelines.
- If issue is resolved, correct and close.
- If issue is not resolved, begin Tertiary education.

**48a. Appropriate refrigerators/freezers are used to store vaccine.**

- On-site visit recommended at 3 months following Secondary Education to check for proper refrigeration/freezer equipment.
- If issue is resolved, correct and close.
- If issue is not resolved, begin Tertiary education.

**50d. From the logs provided, all recorded refrigerator temperatures are within the recommended range.**

- Provide appropriate education associated with high-risk non-compliance issue using memos, TVFC guidelines.
- If vaccine loss occurs due to inappropriate temperatures, an on-site education visit is recommended to ensure that the equipment is approved for vaccine storage and to authorize a new order.
- New/replacement or repaired Refrigeration/freezer units require five working days of temperature monitoring prior to receiving TVFC vaccine.
- If issue is resolved, correct and close.
- If issue is not resolved, begin Tertiary education.

**51c. From the logs provided, all recorded freezer temperatures are within the recommended range.**

- Same as '50d' above.

If staff identifies chronic offenders for which secondary education and Formal Intervention has proven unsuccessful, they should begin Tertiary Education and continue Follow-up. A chronic offender is defined as a provider that has received a 'No' for three years on one of the identified questions, or has received three separate trainings on the issue with no improvement.

### **Tertiary Education and Follow-up**

- 12. Vaccines provided regardless of inability to pay.**
- 14. Administration fee is less than or equal to the maximum fee.**
- 50a. Refrigerator/freezer temperature log is available for the last three months.**
- 55. A physical inventory of vaccine is done monthly.**
- 57. The loss/gain is less than 5% (Accounting).**
- 59. TVFC vaccines can be distinguished from private stock (no private vaccine, but profile indicates insured children in practice).**
- 61a. All clients are screened for eligibility.**

#### **Education for these questions (12, 14, 50a, 55, 57, 59, 61a):**

- When a provider requires tertiary education, the LHD/HSR must perform on-site initial provider education. This education must include the development of a written corrective action plan.
- If corrective action plan is adhered to and effective, return to routine follow-up.
- If corrective action plan is not effective, notify HSR Manager for recommendation for termination from program and/or referral to Texas State Office of Inspector General (OIG).

#### **48a. Appropriate refrigerators/freezers are used to store vaccine**

- Conduct additional follow-up visit after 3 additional months (6-months since Secondary Education).
- If proper units are in place prior to or at six months, consider issue corrected and return to routine follow-up.
- If proper units are not in place after six months, termination from TVFC is recommended.
- Re-enrollment can occur when proper equipment is purchased, and tested.

#### **50d. From the logs provided, all recorded refrigerator temperatures are within the recommended range.**

- If the unit continues to not maintain appropriate temperatures.
- Remove vaccine immediately and suspend future orders.
- Require new, replacement, or repaired refrigerator/freezer units to be monitored for appropriate temperatures for five working days prior to receiving replacement TVFC vaccine.
- Other improper temperature issues, such as documentation errors, or thermometer reading errors, should be addressed with Secondary Education.
- If temperature issues are resolved, consider issue corrected and return to routine follow-up.
- If issues have not been corrected or additional losses occur, refer to HSR Manager for recommendation for termination from TVFC.
- Re-enrollment can occur when equipment is purchased or repaired and determined safe for vaccine storage.

**51c. From the logs provided, all recorded freezer temperatures are within the recommended range.**

- Same as 50d above.

**2. Extenuating Circumstances Existed**

- Each occurrence will be evaluated on a case-by-case basis.
- Secondary, Tertiary education, or referral to external agency will occur as appropriate.
- For these factors to influence how situation is handled it must be an unusual occurrence

**3. No Previous Compliance Issues**

- Follow Secondary Education steps above.

**II. Non-Compliance Identified By Other Means**

**Secondary Education**

Secondary education should include re-education, and individual training, when necessary. Re-education may be preformed via phone call, letter, or site visit, whichever method is most appropriate and practical. The re-education/training should be performed by the overseeing agency.

**A. High-risk non-compliance issues that require Formal Intervention, Tertiary Education, and follow-up.**

**1. Failure to comply with reporting requirements (Operations Manual, Section Four)**

- Monthly Biological Report (C-33)
- Temperature Recording Form (C-105)
- Biological Order Form (C-68)

**2. Billing for TVFC vaccine (Operations Manual, Section Two, Fraud & Abuse)**

**3. Selling TVFC vaccine (Operations Manual, Section Two, Fraud & Abuse)**

**4. Using TVFC vaccine on non-TVFC eligible children (Operations Manual, Section Two, Fraud & Abuse)**

**5. Failure to comply with site visit requirements (Provider Enrollment Form)**

**6. Failure to complete a Provider Enrollment or Re-enrollment Agreement (Provider Enrollment Form)**

**7. Routine borrowing of TVFC vaccine for use on non-eligible TVFC patients (Operations Manual, Appendix)**

**8. Vaccine Loss (Vaccine Loss Reports)**

- Three or more vaccine losses in a year due to negligence or expiration (excluding influenza vaccines), or
- Two or more negligence or expiration vaccine losses of greater than \$2,000 within one year based on current CDC VFC vaccine price list.

## **B. Correction process**

### **1. Previous Compliance Issues**

If staff identifies a provider for which secondary education has proven unsuccessful, they should begin the next phase of Formal Intervention.

### **Formal Intervention Education**

#### **1. Failure to comply with reporting requirements**

- Monthly Biological Report (C-33)
- Temperature Recording Form (C-105)
- Biological Order Form (C-68)
- Re-train on reporting requirements, and provide appropriate follow-up.
- Document re-training.

#### **2. Billing for TVFC vaccine**

#### **3. Selling TVFC vaccine**

#### **4. Using TVFC vaccine on non-TVFC eligible children**

#### **5. Failure to comply with site visit requirements**

#### **6. Failure to complete a Provider Enrollment or Re-enrollment Agreement**

#### **Education for numbers (2, 3, 4, 5, 6):**

- Provide appropriate education associated with high-risk non-compliance issue using memos, and other TVFC guidelines.
- Document re-education.

#### **7. Routine borrowing of TVFC vaccine for use on non TVFC patients**

- Ensure that provider completes the VFC Vaccine Borrowing Report
- Provide appropriate education associated with high-risk non-compliance issue using memos, and other TVFC guidelines.
- Document re-education.

#### **8. Vaccine Loss (Vaccine Loss Reports)**

- Three or more vaccine losses in a year due to negligence or expiration (excluding influenza vaccines), or
- Two or more negligence or expiration vaccine losses of greater than \$2,000 within one year based on current CDC VFC vaccine price list.
- Provide appropriate education associated with high-risk non-compliance issue using memos, and other TVFC guidelines.
- Ensure that provider has received letter regarding large Losses.
- Issue second level warning letter.
- Approve additional orders only after safe storage for vaccines has been confirmed.

If staff identifies chronic offenders for which Secondary Education and Formal Intervention has proven unsuccessful, they should begin Tertiary Education and Follow-up. A chronic offender is defined as a provider that has received a 'No' for three years on one of the identified questions, or has received three separate trainings on the issue with no improvement.

## **Tertiary Education and follow-up**

### **1. Failure to comply with reporting requirements**

- Monthly Biological Report (C-33)
- Temperature Recording Form (C-105)
- Biological Order Form (C-68)
- Perform on-site provider education. This education must include the development of a written corrective action plan signed by the provider.
- Continued failure to submit an accurate and complete Monthly Biological Report (C-33), Temperature Recording Form (C-105), and Biological Order Form (C-68) within required timeframes will require LHD/HSR to:
  - First month after written corrective action plan, a letter will be sent to notify the signing physician of the consequences of not submitting the accurate and complete reports on time (copy in HSR/LHD file).
  - At the end of the second month, LHD/HSR will contact provider and make arrangements to retrieve all TVFC vaccine.
  - At the end of the third month, if reports are not received, the recommend provider be withdrawn from the TVFC program.
- If accurate and complete reports are received, consider issue corrected and return vaccines to the provider. Provider will remain on probation for six months following the return of the vaccine.
- If reporting issues resume, the provider will be notified that:
  - Reports are not timely, accurate and complete
  - Reports must be received by the end of the month.
  - If reports are not received by deadline, vaccines will be retrieved and provider will be withdrawn from the TVFC program.
- After six-month probationary period is complete, resume routine follow-up.
- HSR and Austin Office must approve provider withdrawal upon receipt and review of Secondary, Formal Intervention, and Tertiary documentation.
- Re-enrollment can occur after provider has been withdrawn from the TVFC for at least 12 months.

### **2. Billing for TVFC vaccine**

### **3. Selling TVFC vaccine**

### **4. Using TVFC vaccine on non-TVFC eligible children**

### **5. Failure to comply with site visit requirements**

### **6. Failure to complete a Provider Enrollment or Re-enrollment Agreement**

### **7. Routine borrowing of TVFC vaccine for use on non TVFC patients**

#### **Education for numbers (2, 3, 4, 5, 6, 7):**

- When a provider requires tertiary education, the LHD/HSR must perform on-site initial provider education. This education must include the development of a written corrective action plan signed by the provider.
- If corrective action plan is adhered to and effective, return to routine follow-up.
- If corrective action plan is not effective, notify HSR Manager for recommendation for termination from program and/or referral to Texas State Office of Inspector General (OIG).

## **8. Vaccine Loss (Vaccine Loss Reports)**

- Three or more vaccine losses in a year due to negligence or expiration (excluding influenza vaccines), or
- Two or more negligence or expiration vaccine losses of greater than \$2,000 within one year based on current CDC VFC vaccine price list.
- When a provider requires Tertiary Education, the LHD/HSR must perform on-site initial provider education. This education must include the development of a written corrective action plan signed by the provider.
- At the time of the visit bring a third level warning letter.
- If another loss occurs within 6 months of the third level warning letter, refer to HSR Manager for recommendation for termination from TVFC.
- If no loss occurs within the next 6 months, continue at second level warning for the next 6 months. If another loss occurs during the second 6 months, repeat level three letter.
- After one year of no losses return, to normal follow-up.
- Re-enrollment can occur after provider has been withdrawn from the TVFC for at least 12 months.

## **2. Extenuating Circumstances Existed**

- Each occurrence will be evaluated on a case-by-case basis.
- Secondary, Tertiary Education, or referral to external agency will occur as appropriate.
- For these factors to influence how situation is handled it must be an unusual occurrence.

## **3. No Previous Compliance Issues**

- Follow Secondary Education steps above.